

Appln. No.: 10/525,992
Amendment dated May 30, 2006
Reply to Office Action of March 31, 2006

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. **(Currently Amended)** An anticonvulsant pharmaceutical composition for nasal administration having ~~a binding affinities~~ affinity for at least one ~~the~~ receptor sites ~~was~~ selected from the group consisting of GABA-A agonist site, Glutamate- AMPA site, Glutamate-Kainate site, Glutamate-NMDA agonistic site, Glutamate-NMDA glycine (strychnine insensitive) site and Sodium channel (site 2), ~~comprising~~ consisting essentially of:

- i. an extract of the pericarp of the fruit of *S.trifoliatius*, comprising from 0.001 to 1.0 (% w/v) of hederagenin, and
- ii. at least one pharmaceutically acceptable additive[s].

2. **(Currently Amended)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, wherein the extract comprises hederagenin in an ~~amounts of~~ from 0.004% to 0.08 (% w/v) ~~of~~.

3. **(Original)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, wherein the said extract is in the form of a lyophilized powder or an aqueous solution.

4. **(Original)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1, being suitable for prophylactic treatment of migraine, mediated through its anticonvulsant activity.

5. **(Currently Amended)** An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1 wherein the least one pharmaceutically acceptable additives, comprise agents is selected from the group consisting of at least one preservative agent, at least

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one agent for adjusting the tonicity[;], at least one agent for adjusting viscosity[;], and at least one agent for adjusting pH and a preservative agent.

6. (Original) An anticonvulsant pharmaceutical composition, for nasal administration according to claim 5 wherein the said agent for adjusting the tonicity, is sodium chloride.

7. (Currently Amended) An anticonvulsant pharmaceutical composition, for nasal administration according to claim 5 wherein the said agent for adjusting the viscosity is selected from the group consisting of xanthan gum, carboxymethyl cellulose, methyl cellulose, hydroxypropyl methyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol and carbomers.

8. (Currently Amended) An anticonvulsant pharmaceutical composition, for nasal administration according to claim 5 wherein the said agent for adjusting the pH is selected from the group consisting of citric acid, sodium citrate, potassium dihydrogen phosphate, acetic acid, sodium acetate and ammonium acetate.

9. (Currently Amended) An anticonvulsant pharmaceutical composition, for nasal administration according to claim 5 wherein the said preservative agent is selected from the group consisting of chlorbutanol, phenyl ethyl alcohol and parabens.

10. (Previously Amended) An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1 wherein the pH, is in the range of between 4.5-6.5.

11. (Currently Amended) An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1 wherein the said composition is in the form selected from the group consisting of nasal drops, nasal sprays, nasal powders, semisolid nasal preparations, nasal washes, and nasal sticks ~~and the like~~.

12. (Currently Amended) A process for preparation of an extract ~~containing 4 to 8 % w/w of hederagenin~~, comprising the steps of:

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- a. extraction of the pericarp of the fruit of *S.trifoliatum* with water or an alcohol or a mixture thereof at ambient to boiling temperature for 0.5 to 24 hours,
- b. lyophilization of the aqueous, alcoholic or aqueous alcoholic extract containing a mixture of saponins to give a lyophilized powder, containing a mixture of saponins, and
- c. reconstitution of the lyophilized extract in water to achieve a concentration of hederagenin between 0.001 to 1.0 (% w/v).

13. (Original) A process according to claim 12, wherein the alcohol is selected from a C₁₋₄ alcohol.

14. (Currently Amended) A process according to ~~anyone of~~ claim 12 wherein the C₁₋₄ alcohol is selected from the group consisting of methanol, ethanol, n-propanol, iso-propanol, n-butanol, iso-butanol and tert- butanol.

15. (Currently Amended) A process for preparation of an anticonvulsant pharmaceutical composition comprising:

- i. adding lyophilized aqueous extract of *S.trifoliatum* as ~~claimed in~~ formed in accordance with the process of claim 12 to a mixture of Chlorobutanol and Phenylethyl alcohol in water and sodium chloride, to get a uniform dispersion,
- ii. filtering;
- iii. mixing above dispersion with dispersion of Xanthan gum in purified water; and
- iv. adjusting the pH between 4.5-6.5.

16. (Currently Amended) ~~An extract~~ A composition according to claim 1 which exhibits *in vitro* receptor binding affinity towards ~~a specific receptors like~~ selected from the group consisting of GABA-A agonistic site, Glutamate NMDA agonistic site, Glutamate NMDA

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Glycine (strychnine insensitive) site and sodium channel (site 2) which have mediatory role in anticonvulsant effect.

17. (Currently Amended) ~~An extract~~ A composition according to claim 1 wherein the *in vivo* anticonvulsant activity in rat ~~of~~ in accordance with a Maximal Electroshock Seizure (MES) test model is exhibited by nasal administration.

18. (Currently Amended) ~~An extract~~ A composition according to claim ~~16~~ 17 wherein the anticonvulsant activity exhibited in the MES Maximal Electroshock Seizure model of rat by intra nasal route of administration is without loss of motor co-ordination in rat in the effective dose range.

19. (Currently Amended) A method of prophylactic treatment of migraine through anticonvulsant activity of the ~~said~~ pharmaceutical composition according to claim 1 by its administration through intranasal route.

20. (New) An anticonvulsant pharmaceutical composition, for nasal administration according to claim 1 wherein the composition comprises pharmaceutically acceptable additives comprising a preservative agent, an agent for adjusting tonicity, an agent for adjusting viscosity, and an agent for adjusting pH.

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